DEC 2 0 2001

K012256

Summary of 510(k) Submission

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1.1 Contact Person

Mike Hammons
Director of Operations

1.2 Manufacturer

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1.3 Type of Submission

Traditional 510(k)

Date of submission: August 10, 2001

Date of revision: November 1, 2001

1.4 Device

510(k) Number:	K012256
Proprietary Name:	Gelbish™ Vascular Dilator
Common/Generic Name:	DILATOR, VESSEL, FOR PERCUTENEOUS CATHETERIZATION
Classification:	Class II
Relevant section:	870.**1310**
Product Code:	DRE
Intended Use:	The VascuMetrix Gelbfish™ Vascular Dilators are to be used over a guidewire to dilate or calibrate blood vessels.

1.5 Predicate Device

510(k) Number:	K974617
Device Name:	Peripheral Vascular Dilator
Manufacturer:	EndoVascular Instruments, Inc.
Common/Generic Name:	DILATOR, VESSEL, FOR PERCUTENEOUS CATHETERIZATION
Classification:	Class II
Relevant section:	870.1310
Product Code:	DRE
Intended Use:	The EndoVascular Instrument Peripheral Vascular Dilator is intended to be used to enlarge or calibrate a vessel.

1.6 Description of the device

The VascuMetrix Gelbfish™ Vascular Dilators consist of a small diameter stainless steel tube with a smooth stainless steel tip welded to one end. The lumen of the tube is large enough to slide over an 0.035" guidewire. The tips are available in ten sizes and can be used to dilate or calibrate the lumen of a blood vessel.

The dilator can be inserted into a blood vessel either through a surgical cutdown or percuteneously. It is intended for use only by physicians using sterile technique. It is shipped sterile and intended as a single use device.

1.7 Comparison to the Predicate Device

The physical chemistry, wall thickness, temper, nominal tensile strength and % elongation of the shafts of the Gelbfish™ Vascular Dilators are identical to the predicate device. The tips are constructed of identical material and the shapes are similar. The strength of the tip-shaft bond of the Gelbfish™ Vascular Dilators is equal to or greater than that of the predicate device.

Physical testing has demonstrated that the Gelbfish™ Vascular Dilators and the predicate device have similar flexibility characteristics and are both adequately flexible and "pushable" for the intended use. The Gelbfish™ Vascular Dilators pose no new safety or efficacy issues.

The indications for use are identical.

1.8 Conclusion:

Comparison of the Gelbfish™ Vascular Dilators to EndoVascular Instrument's Peripheral Vascular Dilator for physical properties, performance characteristics and intended use, indicate that these devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2001

Mr. Mike Hammons
Director of Operations
VascuMetrix, LLC
2824 N. Power Rd.
Suite 113-278
Mesa, AZ 85215

Re: K012256
Trade Name: Gelbish™ Vascular Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catherization.
Regulatory Class: II
Product Code: DRE
Dated: August 10, 2001
Received: August 13, 2001

Dear Mr. Hammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Statement of Intended Use

510(k) Number: K012256

Device Name: Gelbfish™ Vascular Dilator

Indications for Use:

The VascuMetrix Gelbfish™ Vascular Dilators are to be used over a guidewire to dilate or calibrate blood vessels.

Division of Cardiovascular & Respiratory Devices
510(k) Number K012256

Prescription Use X
(Per 21 CFR 801.109)